



Omnibus Autism Proceeding (OAP). Id.

Petitioner's counsel requested that the undersigned defer proceedings and transfer the captioned case into the OAP. Alternatively, petitioner's counsel requested an extension of time within which to file a medical expert opinion. On January 8, 2009, petitioner filed the expert opinion of Dr. Mark Geier, a pediatric geneticist.<sup>2</sup> The filed motion suggests that the requested transfer of this case to the OAP may be moot now due to the filing of Dr. Geier's expert report but, for the sake of completeness, the undersigned addresses petitioner's requested transfer to the OAP.

### **I. Filings Subsequent to Petitioner's Motion**

In response to petitioner's motion and by Order dated October 16, 2008, the undersigned directed petitioner to file a statement, with specific citations to the previously filed medical records, that would support a finding that Child Doe/37's developmental delay might be classified properly as an autism spectrum disorder. By that same order, the undersigned afforded respondent an opportunity to file a response to petitioner's statement.

On November 14, 2008, petitioner timely filed a "Statement Regarding Autism or Neurodevelopmental Disorders Similar to Autism" (hereafter referred to as P's Autism Statement). Two and a half weeks later, respondent timely filed a "Response and Opposition to Petitioner's Motion to Transfer Case into Omnibus Autism Proceeding" (hereafter referred to as R's Transfer Response and Opposition). This aspect of petitioner's motion is now ripe for a ruling.

### **II. Autism General Order #1**

Issued by the Chief Special Master of the Office of Special Masters on July 3, 2002, Autism General Order #1 outlined a procedure and a schedule for addressing, through coordinated proceedings referred to as the Omnibus Autism Proceeding (OAP), numerous filed petitions alleging a causal relationship between certain childhood vaccinations and autistic disorders. Autism General Order #1 at 1-3. The two-step procedure for resolving the filed cases was developed by an informal advisory group comprised of petitioners' counsel and respondent's counsel working with several special

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<sup>2</sup> Additionally, an expert report from a pediatric neurologist was due to be filed on or before March 9, 2009. See Order dated January 9, 2009. By motion filed on March 9, 2009, petitioner's counsel requests an enlargement of time, specifically until May 11, 2009, for the filing of this expert report.

masters from the Office of Special Masters. Id. at 3-4. The first step of the proposed procedure involved hearing evidence to determine “whether the vaccinations in question [could] cause autism and/or similar disorders, and if so in what circumstances.” Id. The second step involved applying the conclusions reached during the general inquiry to individual cases. Id. at 4. The proposed schedule of a two-year time period for meeting the outlined objectives was self-imposed by the Office of Special Masters. Id. at 3.

Procedures also were developed to permit petitioners and prospective petitioners to opt into or to opt out of the OAP. See Autism General Order #1 at 6-7. Petitioners with pending autism-related claims when the OAP was implemented could seek a stay of case-specific proceedings during the course of the OAP and request a transfer into the OAP. Id. at 7. Additionally, prior to the summer of 2007, persons with autism-related claims for which no Vaccine Program petition had yet been filed and who wished to stay any case-specific proceedings during the course of the OAP could file a short-form petition (a sample form of which was attached as Exhibit B to Autism General Order #1) requesting inclusion in the OAP.<sup>3</sup> By filing a short-form petition, the filer represents that: (1) the vaccinee received (while in the United States or otherwise in compliance with the Vaccine Act) one or more vaccines covered under the Vaccine Program; (2) the vaccinee “developed a neurodevelopmental disorder [that consists] of an Autism Spectrum Disorder or a similar disorder;” (3) the vaccine-related injury lasted more than six months; (4) the filing of the petition occurred within three years after either the first symptom of the disorder or the first symptom of a vaccine-caused significant aggravation of the disorder, and (5) the vaccine-related claim is neither the subject of a pending civil action nor the subject of a prior award or settlement. See Autism General Order # 1, Exhibit A.

Autism General Order #1 acknowledged that the need for the coordinated omnibus proceeding arose out of the concern that had developed in recent years that

certain childhood vaccinations might be causing or contributing to an apparent increase in the diagnosis of a type of serious neurodevelopmental disorder known as “autism spectrum disorder,” or “autism” for short. Specifically, it has been alleged that cases of autism, or neurodevelopmental

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<sup>3</sup> Short-form petitions continue to be filed. However, in support of the more recently filed petitions (specifically, those filed since the summer of 2007), petitioners also must file medical records and other documentation supportive of petitioners’ claims. Additionally, after further discussion with petitioners’ and respondent’s counsel, the Office of Special Masters has begun to direct, as of January 2008, the filing of collected medical records and other supporting documentation in the earlier filed cases.

disorders similar to autism, may be caused by Measles-Mumps-Rubella (“MMR”) vaccinations; by the “thimerosal” ingredient contained in certain Diphtheria-Tetanus-Pertussis (“DTP”), Diphtheria-Tetanus-acellular Pertussis (“DtaP”), Hepatitis B, and Hemophilus Influenza Type B (“HIB”) vaccinations; or by some combination of the two.

Autism General Order #1 at 1 (footnote two omitted). As defined in footnote two of Autism General Order #1:

An autism spectrum disorder is a brain disorder affecting a person’s ability to communicate, form relationships, and/or respond appropriately to the environment. Such disorders sometimes result in death. The “spectrum” of such disorders includes relatively high-functioning persons with speech and language intact, as well as persons who are mentally retarded, mute, or with serious language delays. Symptoms may include, but are not limited to, avoidance of eye contact, seeming “deafness,” abrupt loss of language, unawareness of environment, physical abusiveness, inaccessibility, fixation, bizarre behavior, “flapping,” repetitive and/or obsessive behavior, insensitivity to pain, social withdrawal, and extreme sensitivity to sounds, textures, tastes, smells, and light.

Autism General Order #1 at 1-2, n.2 (citing National Institute of Mental Health, Publication 97-4023).

With heavy reliance on the language of footnote two, specifically the described symptoms of an autism spectrum disorder, petitioner requests a transfer of this claim to the OAP.

### **III. The Request to Transfer this Case to the Omnibus Autism Proceeding**

As stated in petitioner’s filing, petitioner’s counsel “respectfully disagrees that the Petitioner has to be classified or diagnosed with Autism Spectrum Disorder” for the case to merit transfer to the OAP.<sup>4</sup> P’s Autism Statement at 1. Rather, counsel asserts, the language contained in the Autism General Order #1, which was filed on July 3, 2002, contemplates that “not only autism, but also other neurodevelopmental disorders similar to autism are [to be] included in the Omnibus Autism Proceedings.” P’s Autism

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<sup>4</sup> Counsel erroneously refers to the vaccinee as the petitioner in this case. Because the vaccinee is a minor, she lacks the legal capacity to prosecute this action on her own. Her mother has filed the Program petition on her behalf and is the petitioner in this case.

Statement at 1-2. Counsel points to footnote 2 in the Autism General Order #1, which lists some of the symptoms that may be exhibited by children who fall within the spectrum of autistic disorders. P's Autism Statement at 2.

Counsel concedes that the vaccinee in this case does not carry a diagnosis of autism. Id. at 2. But, counsel asserts that she “has symptoms of a neurodevelopmental disorder similar to autism as discussed in footnote two” of Autism General Order #1. Id. Pointing to particular records filed on behalf of Child Doe/37, counsel asserts that the records demonstrate that she has developmental delays, gaze fixation problems, periods of unresponsiveness at a time when her hearing test results were normal, behavioral changes that include head-hitting and screaming, difficulty with expressive and receptive language and a slight regression in her speech and language, and sensitivity to touch. Id. at 2-4.

Respondent opposes petitioner's motion and challenges petitioner's interpretation of Autism General Order #1. R's Transfer Response and Opposition at 4. Respondent contends that petitioner's position that “neurodevelopmental disorders similar to autism” are to be included in the OAP is a “mistaken” one. Id. Respondent asserts that the interpretation consistently given to Autism General Order #1 by other special masters considering transfer requests has been more limited. Id. at 4-5 (citing Carrington v. Sec'y of Health and Human Servs., 2007 WL 1342149 (Fed. Cl. Spec. Mstr. Apr. 19, 2007) and Browning v. Sec'y of Health and Human Servs., No. 02-928V, Order of April 4, 2008). Respondent suggests that the proper interpretation to be given to Autism General Order #1 “require[s] a demonstration through the medical records or medical opinion of a condition on the autistic spectrum for the transfer of pending cases into the OAP.” Id. at 4.

The undersigned agrees. The third sentence of Autism General Order #1 does refer to the alleged “cases of autism, or neurodevelopmental disorders similar to autism” that are being filed with the Office of Special Masters. Autism General Order #1 at 1-2. The sentence that precedes that sentence, however, states that the concern about possible vaccine causation driving the filing of Program petitions stems from an “apparent increase in the diagnosis of a type of serious neurodevelopmental disorder known as ‘autism spectrum disorder,’ or ‘autism’ for short.” Id. at 1 (footnote omitted). The language in that sentence suggests to the undersigned that the Program petitions contemplated for transfer into the OAP are those cases involving a diagnosed neurodevelopmental disorder falling within the spectrum of autistic disorders.

Footnote two of Autism General Order #1 provides a definition of the disorder and describes some of the symptoms of the condition. Autism General Order #1 at 1 n.2 (citing National Institute of Mental Health, Publication 97-4023). Although footnote two

identifies symptoms that may be important to consider during an evaluation of the timeliness of the filed petition, that footnote is not intended to be a diagnostic tool for use in determining whether a vaccinee has a neurodevelopmental disorder similar to autism. Rather the diagnosis of a vaccinee's condition must be supplied by either the filed medical records or an offered medical opinion. In this case, the filed medical records do not contain a diagnosis of autism, autism spectrum disorder or an autism-related developmental disorder. The filed medical records do indicate that sometime before the age of ten months, Child Doe/37 presented with developmental delay. See Petitioner's Exhibit 1 at 101. The undersigned addresses, in particular, a record from one of Child Doe/37's orthopedic visits. On August 3, 1999 (when Child Doe/37 was nearly ten months old),<sup>5</sup> Dr. Samuel Rosenfeld, a pediatric orthopedist, examined Child Doe/37 to further evaluate her right hip. Petitioner's Exhibit 1 at 100-102. He discussed, as part of Child Doe/37's medical history, her developmental delay. Id. at 101. He stated that after rolling at two months of age, she failed to "progress[] to any independent sitting activities." Id. at 100. Among his impressions, he listed "[d]evelopmental delays," "seizure disorder," and "right developmental hip dislocation." Id. at 101. Although not the initial diagnostic record of Child Doe/37's developmental delay, the record reflects that by ten months of age, she carried a diagnosis of developmental delay that pertained to her physical limitations rather than the impairments in the social and communication domains that are characteristic of autism. Compare Petitioner's Exhibit 1 at 100 (Child Doe/37's described limitations) with Autism General Order #1 at 1 n.2 (impairments characteristic of an autism spectrum disorder).

As respondent correctly points out in the filed opposition to petitioner's transfer request, Dr. Stuart Stein, the Director of Neurology and Neurology Research at Children's Hospital in Orange County, California, examined Child Doe/37 on three separate occasions in 1999, specifically in January, July and September. See Petitioner's Exhibit 1 at 32-35, 98-99, 103-105. Dr. Stein listed among Child Doe/37's medical conditions a severe seizure disorder, a dislocated right hip, a potential disorder of (or lack of) myelin in the brain,<sup>6</sup> and a potential mitochondrial disorder,<sup>7</sup> but he did not suggest or render a diagnosis of autism spectrum disorder. See generally id.

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<sup>5</sup> Child Doe/37 was born on October 11, 1998. Petition at 1.

<sup>6</sup> Myelin is the substance of the cell membrane that coils to form the myelin sheath; it has a high proportion of lipid to protein and serves as an electrical insulator. Dorland's Illustrated Medical Dictionary 1209 (30th ed. 2003).

<sup>7</sup> Mitochondrial disorders are a group of hereditary diseases caused by genetic mutation of mitochondrial DNA. Stedman's Medical Dictionary 569 (28th ed. 2006).

Although the medical records indicate that Child Doe/37 has certain neurological problems and that she manifests some of the traits of an autistic child, she has not received an autism-related diagnosis. Neither petitioner's counsel nor the undersigned can make a diagnosis that Child Doe/37's own treating doctors have not made.

Without a diagnosis on the spectrum of autistic disorders in this case, the evidence adduced in the test cases that have been heard on the second theory of general causation examining whether the thimerosal component of vaccinations can cause autism spectrum disorders lacks relevance. Moreover, having now heard all of the evidence that petitioners in the OAP intend to introduce pertaining to their two general causation theories, the undersigned fails to see how either of the two theories--whether or not the theories are successful--would apply to this case. The OAP test cases were heard not only for the specific purpose of resolving the individually considered test cases, but also for the general purpose of developing a body of evidence that could be applied to resolve other pending autism claims. In the absence of an autism-related diagnosis, a transfer of this case to the OAP would fail to meet the objectives of the OAP. Accordingly, the undersigned declines to exercise her discretion to transfer this case to the OAP, and petitioner's motion to transfer this case to the OAP is **DENIED**.

#### **IV. Conclusion**

For the reasons stated in this order, petitioner's motion to transfer this case to the OAP is **DENIED**. After the filing of the report from petitioner's expert in pediatric neurology, and **by no later than May 22, 2009**, the parties shall contact chambers to arrange a status conference to address the filed expert reports and to schedule the filing of respondent's expert reports. Petitioner's motion for extension of time was granted, as reflected in an order of this same date.

**IT IS SO ORDERED.**

s/Patricia E. Campbell-Smith  
Patricia E. Campbell-Smith  
Special Master